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[REDACTED] EXAMINER

KRUSE, DAVID H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1638 | |

DATE MAILED: 12/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

| Office Action Summary | Application No. | Applicant(s) |
|-----------------------|---------------------------|------------------------|
| | 09/759,704 | SWANSON, BRIAN DOUGLAS |
| | Examiner David H Kruse | Art Unit 1638 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 October 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1,2,4-8,21 and 23-27 is/are allowed.
- 6) Claim(s) 3, 9-20, 22, 28-44 and 47-49 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____ .
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) Interview Summary (PTO-413) Paper No(s). _____ .
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____ .

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed 15 October 2002.
2. Claims 45 and 46 have been canceled as requested.
3. The objection to the disclosure is withdrawn in view of Applicant's amendment.
4. The objection to claims 1, 5, 6, 21, 24, 25, 37 and 40 is withdrawn in view of Applicant's amendment.
5. Those rejections not specifically addressed herein are withdrawn in view of Applicant's amendment and/or remarks.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

7. Claims 3 and 22 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 15 July 2002. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Claims 3 and 22 are indefinite for failing to further limit claims 2 and 21, respectively, from which they depend. Claims 2 and 21 are drawn to a maize plant with a unique genetic and morphological complement, which is male fertile. It is confusing to later characterize the plant of either claim 2 or claim 21 as male sterile.

Art Unit: 1638

Applicant's amendment of claims 3 and 22 is noted. However, the claims remain indefinite. The cancellation of claims 3 and 22, and the submission of the following proposed claims would obviate this rejection:

-- New claim 50. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 2 with a nucleic acid molecule that confers male sterility.

New claim 51. A male-sterile corn plant produced by the method of claim 50.

New claim 52. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 21 with a nucleic acid molecule that confers male sterility.

New claim 53. A male-sterile corn plant produced by the method of claim 52. --.

8. Claims 18 and 47-49 are rejected and claims 19 and 20 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "single gene conversion" in claims 18-20 and 47-49 is used by the claim to mean moving a desired morphological and physiological characteristic via the backcrossing technique or via genetic engineering, (see page 21, 2nd paragraph of the specification) while the accepted meaning is "a nonreciprocal event that occurs at or near the crossover point during reciprocal

recombination." (see Darnell *et al* 1990, In Molecular Cell Biology, Scientific American Books, Inc. New York, New York, specifically page 478).

9. Claims 3, 9-11, 13-20, 22, 28-44 and 47-49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 15 July 2002 for claims 9-11, 13, 14, 17-20, 28-30, 32, 33, 36, 41, 43 and 45-49. Claims 12, 15, 16, 31, 34-35, 37-40, 42 and 46 are now included in the rejection because these claims are broadly drawn to a method of using a multitude of non-exemplified, uncharacterized breeding partners in an unlimited number of crosses, given the open claim language and the failure to specify that an F1 hybrid is produced. Claims 3 and 22 are now included in the rejection because the specification does not describe a plant which is simultaneously male fertile and male sterile. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant notes that a claim to the F1 hybrid made with a deposited inbred was expressly acknowledged without reservation by the United States Supreme Court in *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 50 USPQ 2d 1865, 1873 (S. St. 2001) as directed to the statement by the Supreme Court, "...a utility patent on an inbred plant line protects that line as well as all hybrids produced by crossing that inbred with another plant line." (page 12, 3rd paragraph of the Remarks). The Examiner notes

that this statement by the Supreme Court was made as directed to the patentability of a corn plant under 35 U.S.C. § 101. The Examiner responds that the US Supreme Court also stated at 1873 that “a utility patentable plant must be new, useful, and nonobvious, 35 U.S.C. §§ 101-103” and “to obtain a utility patent, a breeder must describe the plant with sufficient specificity to enable others to “make and use” the invention after the patent term expires. § 112.”. In addition, the US Supreme Court stated, “The description requirement for plants includes a deposit of biological material, for example seed, and mandates that such material be accessible to the public”. While a utility patent protects a hybrid of an inbred plant line under 35 U.S.C. § 101, a claim to such a hybrid must also comply with 35 U.S.C. §§ 103 and 112, first paragraph.

Applicant argues, regarding rejected claims directed to transgenic maize plants produced using Applicant’s PH6WG maize plant, that the genetics of PH6WG will be only minimally affected by the transgene (see page 12, 5th paragraph of the Remarks). The Examiner responds that given the breadth of the claims, said claims would encompass any transgenic plant using Applicant’s PH6WG maize plant comprising, for example, transgenes encoding transcription factors, which are known to be capable of affecting the expressing of multiple genes and expression of multiple traits within a transformed plant.

Applicant argues that claims 30 and 47 have been amended to provide that the transgenic and single gene conversions of PH6WG are essentially unchanged from the corresponding plant or plant parts of PH6WG (page 13, 1st paragraph of the Remarks). This argument is not found to be persuasive for the reason given supra.

Applicant argues that those of ordinary skill in the art use pedigree as a means to characterize lines in reference to their progenitors and that this indicates that a line fewer crosses away from a starting line will be, as a whole, more highly related to the starting line (page 13, 3rd paragraph of the Remarks). The Examiner responds that while Applicant is able to describe a progenitor used to produce the progeny at claims 17, 33, 36 and 43, Applicant fails to adequately describe the progeny in said claims, given the large genus of second progenitor lines that can be used to produce said progeny. The argument related to royalties is irrelevant to the instant rejection (see page 13, end of 3rd paragraph of the remarks).

Applicant argues that pedigree is a distinguishing identifying characteristic in compliance with the written description guidelines (paragraph spanning pages 13-14 of the Remarks). Applicant argues that by limiting the progeny to 2 or less crosses away from PH6WG, that the Examiner's concern that the progeny may be only distantly related to PH6WG is addressed (page 14, 2nd paragraph of the Remarks). Applicant cites *Enzo Biochem Inc. v. Gen-Probe Inc.* U.S. Court of Appeals Federal Circuit, 63 USPQ 2d 1609 (page 14, 2nd paragraph of the Remarks). The Examiner responds that this argument is not found to be persuasive in the instant case. The Examiner does not reject the deposited line PH6WG for lack of written description. Applicant states in the paragraph spanning pages 6-7 of the specification that neither the genotypes of the breeding cross parents nor the desired genotype to be selected is known in detail and that it is not known how the genotype would react with the environment. Applicant also states that a breeder of ordinary skill in the art would be unable to recreate the same

Art Unit: 1638

line twice from the very same original parents as the breeder is unable to direct how the genomes combine or how they will interact with the environmental conditions. Hence, each new maize inbred line is unique and unpredicted. In the same way one of ordinary skill in the art cannot inherently envision what the progeny resulting from the cross of Applicant's PH6WG with another maize plant would be, either said progeny's genotype or phenotype. The U.S. Court of Appeals Federal Circuit's also states at 1617 that a showing of "possession" is ancillary to the *statutory* mandate that the specification will contain a written description of the invention and that a showing of possession alone does not cure the lack of written description of the specification, as required by statute.

Applicant argues that one of ordinary skill in the art would know if PH6WG were utilized in a breeding program by looking at the breeding records and therefore would know if a progeny were derived from PH6WG (page 15, 1st paragraph of the Remarks). This argument is not found to be persuasive because it assumes that one of skill in the art would have access to such breeding records. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described, a breeding record merely describes what a plant does, crosses with another plant, not what it is.

Applicant argues that a progeny plant could not be independently derived without the use of PH6WG and that the claims are drawn to only a limited scope of progeny, progeny which but for Applicant's creation of PH6WG could never have existed (page 15, 2nd paragraph of the Remarks). This argument appears to be irrelevant to an

argument of written description of progeny plants produced from Applicant's deposited line PH6WG.

As directed to claim 14, Applicant argues that claim 14 as amended contains a comparative basis and adequately defines the PH6WG progeny maize plants (page 17, 1st paragraph of the remarks). Applicant states that one reason for using traits as a means of description is because it was, and still is, technologically impossible to sequence the entire genome of a specific [plant] variety (page 16, 1st paragraph of the Remarks). Applicant argues that the fact that technological tools do not exist to fully describe the unique characteristics of the full genome of PH6WG does not make the progeny lines derived therefrom any less entitled to adequate patent protection (page 16, 2nd paragraph of the Remarks). Applicant also argues that the claims are not broadly drawn to any plants expressing the listed traits, but to a subset of the progeny of PH6WG that express those traits (page 17, 2nd paragraph of the Remarks). The Examiner maintains, as directed to claim 14, that over an undetermined number of generations, the identifying characteristics of each generation become highly unpredictable, especially in view of the fact that the breadth of the identifying characteristics of the progeny plants are not described in the specification. The Examiner reiterates that neither the individual traits themselves, nor their degree of expression, appear to be unique to the deposited maize line PH6WG, hence one would not recognize such a progeny maize plant based to a degree of expression of a trait, especial a trait that would be controlled by multiple genetic factors both quantitatively and qualitatively.

10. Claims 30-32 and 47-49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claims 30 and 47 appears to be new matter, which is not permitted under 37 CFR § 1.53(b) and 35 USC § 132(a). The Examiner notes that Applicant does not specifically point out in the response where the amendment to claims 30 and 47 is supported in the instant specification. Hence, it is unclear from the instant specification that Applicant had contemplated such a claim limitation at the time of Applicant's invention.

11. Claims 12, 31 and 42 remain rejected and claims 3, 9-11, 13-20, 28-30, 32-41, ~~43-44~~ and 47-49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 15 July 2002, and modified as set forth below. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant argues that one of ordinary skill in the art would know if they were using or one could easily identify if they were using PH6WG, PH6WG further containing a transgene, and PH6WG further containing a singe gene conversion to develop a hybrid. Applicant argues that all F1 plants would have essentially the same genetic markers as the deposited PH6WG and that it is well known to anyone skilled in the art

that a hybrid has a genome with one set of alleles from each inbred (page 17, 5th paragraph of the Remarks). Applicant has submitted the reference Berry *et al* (2000, Genetics 161: 813-824) herein made of record in the instant application. Applicant argues that Berry *et al* showed that using 100 SSR loci markers resulted in correct parental ranking of inbreds for 53 out of 54 hybrids and that any breeder of ordinary skill in the art would know the identify of both parents used to produce a hybrid (page 18, 1st paragraph of the Remarks). Applicant also argues that one of ordinary skill in the art would also know how to cross PH6WG containing a transgene or singe gene conversion with another plant to produce a hybrid (page 18, 2nd paragraph of the Remarks). This argument is not found to be persuasive because Applicant does not teach which markers to use in an identification method that would be useful for reliably identifying a maize plant as a progeny of PH6WG, and not, for instance, maize plant PHR61.

Additionally, claims 9-11, 13, 14, 17-20, 28-30, 32, 33, 36-39 41, 43 and 47-49 are rejected as not enabled for lack of written description because Applicant has not adequately taught one of skill in the art how to make and use the claimed invention.

Hunsperger *et al* (1996, U.S. Patent 5,523,520), Kraft *et al* (2000, Theor. Appl. Genet. 101:323-326), and Eshed *et al* (1996, Genetics 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger *et al* teach that the introgression of a gene in one genetic background in any plant of the

same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46). In particular, Hunsperger *et al* teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41).

Kraft *et al* teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype-specific and loci-dependent in nature (see, e.g., page 323). Kraft *et al* teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials, which contributes to the unpredictability of the effect. Eshed *et al* teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate the genes responsible for a multitude of non-exemplified traits, to evaluate the ability of these genes to be successfully expressed in various maize genetic backgrounds, or to obtain "single gene conversion" plants which contain a

Art Unit: 1638

multitude of introgressed traits, but otherwise maintain all of the genetic and physiological and morphological characteristics of the parent plant.

At claim 14, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's inventions to screen through a myriad of maize plants wherein at least one ancestor of said maize plant is the maize plant of claim 2 and identify those maize plants having at least two of the claimed PH6WG traits. Applicant states in the specification that the breeder is unable to direct how the genomes combine or how they will interact with the environmental conditions (paragraph spanning pages 6-7 of the specification).

At claims 18-20, 37-39 and 47-49, the claimed method for producing inbred PH6WG and PH6WG maize plants or parts thereof comprising one or more "single gene conversion" are not enabled in view of Applicant's specification because Applicant states that neither the genotypes of the breeding cross parents nor the desired genotype to be selected is known in detail and that it is not known how the genotype would react with the environment. Applicant also states that a breeder of ordinary skill in the art would be unable to recreate the same line twice from the very same original parents as the breeder is unable to direct how the genomes combine or how they will interact with the environmental conditions (paragraph spanning pages 6-7 of the specification). Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to reproduce the deposited PH6WG maize inbred plant from a hybrid, one of whose parents is inbred PH6WG or said plant having a "single gene conversion" as claimed.

The following amendments would obviate the rejections under 35 USC § 112, first paragraph:

Replace claims 3 and 22 with claims 50-53 as suggested to overcome the rejection under 35 USC § 112, second paragraph.

Cancel claims 9-20, 28-44 and 47-49.

Submit new claims 54-63 below (support for said claims can be found in the specification, pages 28-33).

-- New claim 54. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers herbicide resistance.

New claim 55. An herbicide resistant corn plant produced by the method of claim 54.

New claim 56. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers insect resistance.

New claim 57. An insect resistant corn plant produced by the method of claim 56.

New claim 58. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers disease resistance.

New claim 59. A disease resistant corn plant produced by the method of claim 58.

New claim 60. A method of producing a corn plant with decreased phytate content comprising transforming the corn plant of claim 2 with a transgene encoding phytase.

New claim 61. A corn plant with decreased phytate content, produced by the method of claim 60.

New claim 62. A method of producing a corn plant with modified fatty acid or carbohydrate metabolism comprising transforming the corn plant of claim 2 with one or more transgenes encoding a protein selected from the group consisting of stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase, and starch branching enzyme.

New claim 63. A corn plant produced by the method of claim 62. --

Claim Rejections - 35 USC § 102/103

12. Claims 14, 41 and 43 remain rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Hoffbeck (US Patent 5,463,173, number corrected from that of the previous Office action mailed 15 July 2002). This rejection is repeated for the reason of record as set forth in the last Office action mailed 15 July 2002 for claims 9, 10, 14, 17, 28, 29, 33, 36, 41, 43, 45 and 46. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant argues that hybrids would be distinguishable both through genetics and morphologically and physiologically because PH6WG is not PHR61, nor is PH6WG a minor or obvious derivative of PHR61 (page 19, 2nd paragraph of the Remarks).

Art Unit: 1638

Applicant again cites Berry *et al* (2000) and argues that any breeder of ordinary skill in the art would know the identity of both parents used to produce a hybrid (paragraph spanning pages 19-20 of the Remarks). The Examiner responds that Berry also teaches that as one of skill in the art moves further from the original parental lines, the ability to determine those original parental lines decreases rapidly from about 96% for the F1 generation (see page 820, left column, 2nd paragraph) to only about 7% for the F3 generation (see page 822, left column, 2nd paragraph). Hence, it remains the Examiner's opinion that the maize plants at claims 14, 32, 41 and 43 would have been anticipated by or in the alternative obvious over the teachings of Hoffbeck.

Conclusion

13. This Office Action is non-final.
14. Claims 1, 2, 4-8, 21 and 23-27 are allowed.
15. Claims 3, 9-20, 22, 28-44 and 47-49 remain rejected.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
19 December 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

